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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,806	03/31/2004	Constantin Cope	8627/487 (PA-5391RFB)	7536
27879 7590 08/18/2008 INDIANAPOLIS OFFICE: 27879 BRINKS HOFER GILSON & LIONE ONE INDIANA SQUARE, SUITE 1600 INDIANAPOLIS, IN 46204-2033				
EXAMINER BOUCHELLE, LAURA A				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
08/18/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/813,806

**Applicant(s)**

COPE ET AL.

**Examiner**

LAURA A. BOUCHELLE

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7-14, 16-24 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 11-14, 16-22, 24 and 29-32 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

In response to Amendment after Final filed 3/28/08 the finality of the previous action has been withdrawn.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 7, 8, 11, 13, 16, 17, 20-22, 24, 29, 30, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Clinton et al (US 5295970). Clinton discloses an apparatus for vascular guidewire insertion comprising a needle assembly comprising an elongate needle 12 and a needle hub 18, a needle hub attachment assembly 20 configured to leak-free engagement (luer lock 40) with the needle hub, and comprising a chamber 30 for receiving body fluid, an assembly 46 including a hemostatic segment 52 comprising a valve 62 having an opening to permit passage of a guidewire 64, the distal end sized for leak free engagement with the proximal end of the hub attachment assembly, the hemostatic segment tapers to an end hole (portion labeled 62 is a funnel) having substantially the same diameter as the guidewire. See Figs. 2, 5. The valve is elastomeric and tapers to an end hole having a diameter substantially the diameter of the guidewire (col. 6, lines 13-24). The needle hub attachment assembly 22 is formed of a transparent material (col. 5, lines 22-24). The needle assembly includes a hemostatic segment 50.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 2, 3, 4, 12, 18, 19, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clinton in view of Raulerson et al (US 6551281). Claims 2, 3, 4 differ from Osypka in calling for the hemostatic segment to include a guidewire inserter or holder that is preloaded with a guidewire. Claim 12 calls for the holder to fasten the guidewire in a loop. Raulerson teaches a guidewire advancer comprising a guidewire holder 24 that is preloaded with a guidewire 21 fastened in a loop so that the guidewire can be easily manipulated by the user and remain sterile while it is inserted into the patient through the introducer device 30. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the device of Clinton a preloaded guidewire holder as taught by Raulerson so that the guidewire can be easily manipulated by the user and remain sterile while it is inserted into the patient through the introducer device.
5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clinton. Claim 14 calls for the leak free engagement to comprise a threaded connection. Clinton discloses that the leak free engagement is a luer lock. It is well known in the art to use either a luer lock or a threaded connection to form a leak free engagement between two components. Luer lock and threaded engagements are well known alternatives. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Clinton to include a threaded engagement because it is a well know alternative to a luer lock.

***Allowable Subject Matter***

6. Claims 9, 10, 23 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

7. Applicant's arguments, see pages 8-16, filed 3/28/08, with respect to the rejection(s) of claim(s) 1, 2, 7-10, 14, 16, 17, 18, 21-24, 30 under Osypka have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Clinton as above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

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